## REMARKS

Claims 1-3, 6, 32-34, 47, 50, 54, 57, 58, 61-74, 76-80, 82-101 and 108-110 are pending in this application. Withdrawn method claims 50, 54, 57, 58 and 82-94, directed to non-elected subject matter, are retained for possible rejoinder with pending product claims that are deemed allowable.

### THE REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH- ENABLEMENT

Claims 47, 72, 73 and 76-79 are again rejected under 35 U.S.C. §112, first paragraph, as allegedly not being enabled for their full scope. The Examiner maintains that the specification is only enabling for pharmaceutical compositions of compounds in which the "therapeutic domain" (*i.e.*, the sialidase) is selected from among SEQ ID NO:8 and SEQ ID NO:9, and the "anchoring domain" is selected from among the GAG-binding domains of SEQ ID NOS: 3, 4, 5 or 7.

The Examiner further alleges that Applicant has provided no data to support the fact that a fusion construct as claimed is effective in controlling influenza or other viral infections. Responsive to Applicant's submission of a Declaration of Fang under 37 C.F.R. §1.132, which accompanied the Amendment and Response filed December 22, 2009, the Examiner asserts that the data provided in the Declaration, which showed a cell protection efficacy of 12%-51% against various influenza strains, is insufficient to classify the tested fusion construct as a compound that is capable of preventing an infection.

This rejection is traversed.

**Analysis**

As discussed previously, the question that goes to enablement of the claimed pharmaceutical formulations is whether the specification provides sufficient guidance for one of skill in the art to be able to make and use the pharmaceutical formulations. The specification has provided ample teachings to be able to do so. As discussed, the specification teaches how to make compounds containing a α(2,3)-Gal and/or α(2,6)-Gal bacterial or human sialidase or active portion thereof linked to a GAG-binding protein or peptide containing one of SEQ ID

NOS: 2-7, how to measure the sialidase activity of these compounds including their ability to cleave sialic acid receptors on the surfaces of target cells, and how to test the compounds in infectivity assays. The Declaration of Fang further exemplifies operability of the compounds as pharmaceutical formulations.

**The claims are enablement irrespective of whether prevention of infection is enabled**

The rejected claims are not directed to methods of preventing infection; they are directed to pharmaceutical formulations of compounds that are disclosed and claimed herein. As discussed previously, the specification teaches how to make and use the compounds, how to incorporate the compounds into pharmaceutical formulations, and how to test the pharmaceutical formulations for their activity against pathogenic infection. Thus, Applicant has met the burden of demonstrating that one of skill in the art can make and use the subject matter (pharmaceutical formulations) as claimed. As the specification explains, the claimed pharmaceutical formulations may be used to prevent or treat a variety of bacterial and viral pathogenic infections whose entry into cells is mediated *via* sialic acid receptors, the claims are not limited by use in prevention of any disease or disorder. The enablement analysis must be focused on the product or method defined by the claims. There is nothing in the rejected claims that requires prevention of infection. Thus, the Examiner's focus on whether the claimed compositions **prevent** infection is inapt.

**No factual or evidentiary support is provided for the assertion that a cell protection efficacy of 12%-51% is insufficiently demonstrative of an ability to prevent infection**

Notwithstanding the inaptness of rejecting the pharmaceutical formulation claims for allegedly not enabling the prevention of infection, Applicant additionally submits that the Examiner has provided not provided any reasoned basis for concluding that the data in the Declaration of Fang under 37 C.F.R. §1.132 is inadequate for demonstrating that the rejected claims are not enabled. The law is clear that it is the Examiner's obligation to provide such are reasoned basis. "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the

objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to ***back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statemen***t." *Id.* at 224. (emphasis added). Instead of providing acceptable evidence or reasoning to doubt the truth or accuracy of disclosure or the data presented in Declaration of Fang under 37 C.F.R. §1.132, the Examiner simply asserted that the level of cell protection is inadequate. The Examiner has not explained why the demonstrated level of cell protection is inadequate or what level of cell protection would be satisfactory to demonstrate enablement. For this reason alone, the rejections under 35 U.S.C. §112 should be withdrawn.

**Even if it were proper to use "effectiveness in preventing infection" as the parameter for assessing enablement of the claimed pharmaceutical formulations, the Examiner appears to apply an improper, elevated standard in carrying out such assessment**

To the extent that the Examiner is suggesting that anything near complete efficacy in treatment or prevention of disease is required to demonstrate enablement, the Examiner is applying an improper, elevated standard. "[U]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir.1995). Enablement of the claimed pharmaceutical formulations does not require a perfected clinical regimen, ready for FDA approval (*see*, for example, *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), holding that FDA approval is not a prerequisite for finding utility (operability) within the meaning of the patent laws).

Moreover, the idea that anything near complete efficacy is required to demonstrate enablement of a pharmaceutical composition is completely at odds with pharmaceuitcal efficacy that is viewed as useful. As the attached publications by Jefferson et al. and Szilagyi et al. show (Jefferson et al., *Lancet,* 366:1165-1174 (2005); Exhibit A and Szilagyi et al., *Arch. Ped. Adolesc. Med.*, 162:943-951 (2008); Exhibit B), influenza vaccines reduce the incidence of influenza and/or its associated complications, such as the requirement for hospitalization, the

development of pneumonia or mortality; they do not eliminate their occurrence and, in fact, are far less than completely effective in protecting against influenza. Nonetheless, they are approved by the FDA and used because of their ability to reduce the risk of influenza infection in the general population and especially in vulnerable populations such as young children (Szilagyi et al.) and elderly adults (Jefferson et al.).

In light of the above, Applicant respectfully submits that claims 47, 72, 73 and 77-79, directed to pharmaceutical formulations of a compound containing a bacterial or human sialidase or active portion thereof with sialidase activity that cleaves α(2,3)-Gal and/or α(2,6)-Gal linkages, are enabled for their scope. In addition, although not required, the Declaration of Fang has demonstrated operability of a use of the claimed pharmaceutical formulations in treatment or prevention of influenza. There is no reason why, given these teachings and the knowledge of those of skill in the art, one would not be able to make and use, without undue experimentation, the pharmaceutical formulations as claimed.

**THE REJECTION UNDER 37 C.F.R. §1.75 – "SUBSTANTIALLY DUPLICATIVE" CLAIMS**

Claims 99-101 and 108-110 are objected to as being substantial duplicates of Claims 1, 6, 32-34 and 61-65. This rejection will be addressed as appropriate upon indication that the pending claims are otherwise deemed allowable.

**THE REJECTION OF CLAIMS 1-3, 6, 32-34, 47, 61-74, 76-80 AND 94-101 UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE-PATENTING**

Claims 1-3, 6-10, 12-14, 22, 24, 31-34, 47, 61-79 and 94-98 are provisionally rejected under the judicially created doctrine of obviousness-type double-patenting over Claims 141-147, 149, 151, 162-169 and 171 of co-pending Application Serial No. 10/939,262, now issued U.S. Patent No. 7,807,174. This rejection will be addressed as appropriate upon indication that the pending claims are otherwise deemed allowable.

## CONCLUSION

In view of the remarks herein, entry of the Response is respectfully requested.

The fees in the amount of $555.00 for the Petition for Extension of Time fee are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing attorney docket no. 21865-0002001.

Respectfully submitted,

Date: 18 November 2010

/Anita L. Meiklejohn/
Anita Meiklejohn, Ph.D.
Reg. No. 35,283

**Customer Number 20985**
Fish & Richardson P.C.
Telephone: (617) 542-5070
Facsimile: (877) 769-7945